

Service Area Office, East
Department of Veterans Affairs
323 North Shore Drive, Suite 500
Pittsburgh, PA 15212

Memorandum 2011-003
December 28, 2010

LIMITED SOURCES JUSTIFICATION
ORDER >\$3,000
FAR PART 8.405-6

2237 Transaction # or Vista Equipment Transaction #: _____

This acquisition is conducted under the authority of the Multiple Award Schedule Program. The material or service listed in par. 3 below is sole source, therefore, consideration of the number of contractors required by FAR Subpart 8.4 – Federal Supply Schedules, is precluded for the reasons indicated below.

Restricted to the following source: Provide original manufacturer's name for material or contractor's name for service. (If a sole source manufacturer distributes via dealers, ALSO provide dealer information.)

Manufacturer/Contractor: Immucor, Inc.

Manufacturer/Contractor POC & phone number: 800-829-2553

Mfgr/Contractor Address: 3130 Gateway Drive, PO Box 5625, Norcross, GA 30091

Dealer/Rep address/phone number: G. Riley, 855-466-8267, griley@immucor.com

☒ The requested material or service represents the minimum requirements of the Government.

(1) AGENCY AND CONTRACTING ACTIVITY:

Department of Veterans Affairs – NCO 2
222 Richmond Ave Bldg 3 Rm 103
Batavia, NY 14020
02

VISN:

(2) NATURE AND/OR DESCRIPTION OF ACTION BEING APPROVED:

This requirement is for red blood cell reagents which are utilized to test blood for certain illnesses/diseases prior to use in transfusions. This will be a firm-fixed price Blanket Purchase Agreement (BPA) for these laboratory testing reagents. This requirement is meant to establish a multi-year contracting vehicle for the laboratory to place orders against annually or as needed.

(3) (a) A DESCRIPTION OF THE SUPPLIES OR SERVICES REQUIRED TO MEET THE AGENCY'S NEED:

All required items for testing are on FSS contract # V797P-5944X, which currently expires June 30, 2015. These items are as follows:

Coombs Control Cells (#2226) - (26) 10 mL vials/year
Coombs Control Cells, Strong (#2224) - (66) 10 mL vials/year
Panocell 16 (#2332) - (39) 16 x 3 mL vials/year
Panoscreen I, II (#2380) - (26) 2 x 10 mL vials/year
Reference Cells A2 (#2342) - (39) 10 mL vials/year
Antibody Detection (I, II, and III), Panoscreen 2-4% (#2381) - (13) 3 x 10 mL vials/year
Coombs Complement (#7930) - (77) 3 mL vials/year
Quality Control, 2 Level (#2400) - (39) 2 x 11.5 mL vials/year
Reverse Grouping Cells (#2345) - (91) 2 x 10 mL sets/year

Per the NAC Contracting Officer, this contract will be extended and pricing updated once it is received from the

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contractor prior to the expiration date. This requirement is anticipated to be a Blanket Purchase Agreement against the FSS contract.

(b) ESTIMATED DOLLAR VALUE: _____

(c) REQUIRED DELIVERY DATE: 7/1/15 and negotiated dates thereafter during life of BPA

(4) IDENTIFICATION OF THE JUSTIFICATION RATIONALE (SEE FAR 8.405-6), AND IF APPLICABLE, A DEMONSTRATION OF THE PROPOSED CONTRACTOR'S UNIQUE QUALIFICATIONS TO PROVIDE THE REQUIRED SUPPLY OR SERVICE.

☒ Specific characteristics of the material or service that limit the availability to a sole source (unique features, function of the item, etc.). Describe in detail why only this suggested source can furnish the requirements to the exclusion of other sources.

Immucor is currently the only FSS schedule holder (V797P-5944X) producing all of the required reagents listed above at the quality and quantity levels required by the VA in VISN 2. These products are currently on a mandatory Schedule 65 under SIN 555-1 (Blood Bank). After looking through the price lists on the NAC website, it appears that no other company distributes these specific products. Therefore, Immucor appears to be the only source of supply for these products. Moreover, after significant discussion and analysis with the VISN 2 Laboratory group, there are no other comparable products with the same quality and quantity levels on a VA contract.

☐ A patent, copyright or proprietary data limits competition. The proprietary data is: _____

☐ These are "direct replacements" parts/components for existing equipment. _____

☒ The material/service must be compatible in all aspects (form, fit and function) with existing systems presently installed/performing. Describe the equipment/function you have now and how the new item/service must coordinate, connect, or interface with the existing system.

The regents listed above are part of a unique testing assay utilized by the laboratories throughout VISN 2. Recently, the VISN 2 laboratories tested a few different providers with FSS contracts to see if their new testing assays met the same quality and quantity standards as the current provider. With the exception of Immucor, none of the other FSS vendors provide testing materials that meet the same level of quality and quantity that the current provider (Immucor) provides. Ultimately, there are no items that can be substituted for the requested reagents at this time.

☐ The new work is a logical follow-on to an original Federal Supply Schedule order provided that the original order was placed in accordance with the applicable Federal Supply Schedule ordering procedures. The original order must not have been previously issued under sole source or limited source procedures. _____

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☐ An urgent and compelling need exists, and following the ordering procedures would result in unacceptable delays.

(5) DESCRIBE WHY YOU BELIEVE THE ORDER REPRESENTS THE BEST VALUE CONSISTENT WITH FAR 8.404(d) TO AID THE CONTRACTING OFFICER IN MAKING THIS BEST VALUE DETERMINATION:

In accordance with FAR 8.405-6(a)(i)(B), only one source holding a FSS contract is capable of supplying these items. See above for more details. Moreover, Immucor has a strong history of positive past performance. There are currently no terminations listed in the FAPIIS database and no recorded instances of defective pricing. Additionally, Immucor's delivery system is highly efficient and therefore is able to provide these testing supplies quickly. Finally, when negotiated, the Contracting Officer for the FSS contract sought the best value for these tests. In addition to this, the Contracting Officer for this requirement will seek additional discounts if possible for this requirement.

(6) DESCRIBE THE MARKET RESEARCH CONDUCTED AMONG SCHEDULE HOLDERS AND THE RESULTS OR A STATEMENT OF THE REASON MARKET RESEARCH WAS NOT CONDUCTED:

These blood testing items have been used throughout VISN 2 for many years. Most recently, these supplies were purchased against the Immucor FSS contract (V797P-5944X) as a task order (VA528-15-F-0454) with deliveries through the current end date of the FSS contract (June 30, 2015). This order was written against the mandatory Schedule 65 FSS contract. Only one schedule holder under SIN 555-1 (Blood Bank) provides these testing supplies at a level of quality and quantity that is acceptable to the VISN 2 laboratories: Immucor, Inc. Additional searches were conducted to see what other companies could provide testing materials of the same quality and quantity as the current provider. As a result, the VISN 2 laboratories recently received and tested reagent supplies from other vendors listed under SIN 555-1 that appeared to provide most of the same general type of testing materials. As a result of these tests, no other company was identified as having supplies of the same quality or quantity as Immucor with the most significant concern being false positives or lack of indication with some of the newly tested reagents. Further, the most recent procurement of these testing supplies solicited and awarded in November 2015 concluded the same procurement decision. At that time, a limited source justification was approved. The market research for the award in November 2015 included contacting major medical distributors, other companies listed under FSS SIN 555-1, and a review of DLA's Medical Product Database (MedPDB) which showed that all VA hospitals in the nation currently procure these reagents directly from Immucor and no distributor other than Immucor was on file for these items. In sum, the market research demonstrates that only one supplier (Immucor, Inc.) has acceptable quality and quantity of testing reagents required for blood testing prior to transfusion use in VISN 2.

(7) ANY OTHER FACTS SUPPORTING THE JUSTIFICATION:

(8) A STATEMENT OF THE ACTIONS, IF ANY, THE AGENCY MAY TAKE TO REMOVE OR OVERCOME ANY BARRIERS THAT LED TO THE RESTRICTED CONSIDERATION BEFORE ANY SUBSEQUENT ACQUISITION FOR THE SUPPLIES OR SERVICES IS MADE:

There is no known action that will overcome this barrier other than another provider entering the market with an equal or superior product that can meet VISN 2's quality and quantity requirements. The VA will continue to

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monitor the market for red blood cell testing reagents that are of acceptable quality and quantity from other manufacturers and encourage competition wherever possible.

(9) **REQUIREMENTS CERTIFICATION:** I certify that the requirement outlined in this justification is a bonafide need of the Department of Veterans Affairs and that the supporting data under my cognizance, which are included in the justification, are accurate and complete to the best of my knowledge. I understand that processing of this limited sources justification restricts consideration of Federal Supply Schedule contractors to fewer than the number required by FAR Subpart 8.4.

_____ SIGNATURE		4/14/2015 DATE
_____ NAME	Medical Technologist, COR TITLE	Lab Service-113 SERVICE LINE/SECTION
Albany-Stratton VA Medical Center FACILITY		

(10) **APPROVALS IN ACCORDANCE WITH FAR 8.405-6(h):**

a. **CONTRACTING OFFICER'S CERTIFICATION (required):** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

_____ CONTRACTING OFFICER'S SIGNATURE	4/14/2015 DATE
_____ CONTRACTING OFFICER	NCO 2 FACILITY

HIGHER LEVEL APPROVAL (For orders over \$650,000): ☐ REQUIRED ☒ NOT REQUIRED

b. **ONE LEVEL ABOVE CONTRACTING OFFICER:** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief. **This signature may be the VISN NCM if the Contracting Officer and Contracting Supervisor is the same individual.*

_____ SIGNATURE	_____ DATE
_____, NCO 2 Supply Branch Chief	
NAME AND TITLE	

_____ SIGNATURE	_____ DATE
_____, NCO 2 Division Chief	
NAME AND TITLE	

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c. **NCM** : I certify the justification meets requirements for restricting consideration of Federal Supply Schedule contractors to fewer than the number required by FAR Subpart 8.4.

DATE

d. **SAO EAST** : I certify the justification meets requirements for restricting consideration of the Federal Supply Schedule contractors to fewer than the number required by FAR Subpart 8.4.

DATE

Director, SAO East

e. **VHA HCA'S REVIEW AND APPROVAL(over \$650,000 to \$12.5 million)**: I have reviewed the foregoing justification and find it to be complete and accurate to the best of my knowledge and belief and approve for restricting consideration of the Federal Supply Schedule contractors to fewer than the number required by FAR Subpart 8.4

DATE

Head of Contracting Activity (HCA)

f. **VHA Senior Procurement Executive Approval (over \$12.5 million)**: I have reviewed the foregoing justification and find it to be complete and accurate to the best of my knowledge and belief and approve for other than full and open competition.

Date

Deputy Assistant Secretary
Office of Acquisition and Logistics
Senior Procurement Executive (SPE)